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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/628,693	07/28/00	HAROCHE J	03495.0193

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EXAMINER	
PAK, Y	
ART UNIT	**PAPER NUMBER**
1652	9

DATE MAILED: 11/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/628,693	HAROCHE ET AL.	
	Examiner	Art Unit	
	Yong Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *10-22 and 33-41* is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 2* is/are allowed.

6)☒ Claim(s) *3-9 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response to the Restriction Requirement filed on September 28, 2001 has been entered.

Claims 1-41 are pending.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-9 and 23-32) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that examinations of Inventions II-VIII in addition to Invention I do not require an undue burden on the examiner. This is not found persuasive. Because of the recognized divergent subject matter between Inventions I-VIII and their different classification of subclass, an unduly extensive and burdensome search is required for Inventions I-VIII that is not required for Invention I.

Claims 10-22 and 33-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made **FINAL**.

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on July 28, 2000 have been approved.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-7 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 is drawn to DNA encoding a vatD polypeptide. Therefore, this claim is drawn to a genus of vatD genes, with any structure and from any source. The specification only teaches DNA encoding vatD of SEQ ID NO:1 from *Enterococcus faecium.* One representative species is not enough to describe the whole genus and there is no evidence on the record of the relationship between the structure of an *E. faecium* vatD and the structure of a vatD from another source. Therefore, the specification fails to describe other representative species of the genus of DNA encoding a vatD polypeptide.

Claim 6 is drawn to DNA encoding allelic variants of vatD polypeptide polypeptides. Therefore, these claims are drawn to a subgenus of allelic DNAs that encode polypeptides comprising SEQ ID NO:1. The specification discloses only one allele within the scope of the genus, SEQ ID NO:2. There is no description of how the structure of SEQ ID NO:2 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. Therefore, the specification fails to describe common attributes of the genus.

Given this lack of the description of the representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 6-7 and 23-25.

Claims 6-7 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding a vatD of SEQ ID NO: 2, does not reasonably provide enablement for DNA encoding vatD not homologous to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Despite knowledge in the art for the isolation of amino acids, the specification fails to provide guidance regarding how to isolate other DNA encoding a vatD whose sequence is not homologous to SEQ ID NO:2. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other carbonyl reductase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to make DNA encoding vatD not homologous to SEQ ID NO:2 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the plasmid deposited at CNCM under the Accession Number I-2247 is required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. § 1.802.

The specification does not provide a repeatable process for obtaining the microorganism(s) and it is not apparent if the microorganism(s) is/are readily available to the public. The specification must contain the date that the microorganism(s) was/were deposited, the name of the microorganism(s) and the address of where the microorganism(s) was/were deposited.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;(c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-9 and 23-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, the exact hybridization condition is unclear. Different nucleic acids hybridize to a DNA sequence under different conditions. Therefore, the scope of DNA molecules encompassed by claim 3 is unclear.

In claim 4, a colon after "NO" in line 3 is missing. Further, the language of claim 4 is confusing because it is unclear if applicants are claiming nucleic acid molecules that hybridizes to SEQ ID NO:15.

Claim 5 is unclear because SEQ ID NO: 5 and 7 are amino acid sequences and the claim is drawn to nucleic acid molecules and degenerate nucleic acid molecules.

In claim 6, the phrase "vatD polypeptide DNA" is confusing. This rejection can be overcome by amending claim 6 as "DNA encoding a vatD polypeptide", for example.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Arden et al.

Werner et al. teach a polynucleotide that is 99.3% and 87.1% identical to SEQ ID NO:1 and SEQ ID NO:15, respectively, of the instant invention. The DNA of Werner et al. hybridizes to SEQ ID NO:1 and 15 under conditions of moderate stringency and can be construed as a homolog or variant of a DNA encoding a vatD polypeptide. Werner et al. Therefore, the teachings of Arden et al. anticipate claims 3-4 and 6.

Claim 5 is rejected under 35 U.S.C. 102(a) as being anticipated by Allignet et al.

Allignet et al. teach a polynucleotide that is 100% identical to SEQ ID NO:6 and 8 of the instant invention (page 10, line 15-19). Allignet et al. also teach a polypeptide that is 100% identical to SEQ ID NO:5 and 7 of the instant invention (page 10, line 15-19). Therefore, the teaching of Allignet et al. anticipates claim 5.

Claims 6-7 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Rende-Fournier et al.

Rende-Fournier et al. (form PTO-1449) teach a polynucleotide (*satA*) encoding a streptogramin A acetyltransferase from Enterococcus faecium (Figure 2, page 2122). Art teaches that *vatD* and *satA* are synonymous (Soltani et al. p. 645, 1st paragraph and Simjee et al. p. 2931, 2nd paragraph). Rende-Fournier et al. also teach a vector comprising the satA gene, a host cell transformed with said vector and a method of producing the satA polypeptide. Therefore, the teachings of Rende-Fournier et al. anticipate claims 6-7 and 23-25.

Claims 1-2 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3173.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

PONNATHAPU ACHUTAMURTHY
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October 31, 2001